

### **REMARKS**

To further prosecution, claim 14 has been amended to recite, "A thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers, said thermoplastically processable material being obtained by extrusion at a temperature of from 80 °C to 200 °C in the presence of water and/or a plasticizer containing hydroxyl groups." Support is found in the Specification at, for example, the paragraph bridging pages 4 – 5 of published WO 00/54578. Support is also found in original claim 6. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973); and MPEP 608.01(o) and (l).

### ***Anticipation Rejections***

1. Claim 14 in view of Goehl

Claim 14 was rejected under 35 U.S.C. § 102(b) as being anticipated by EP 011663 ("Goehl"). (Paper No. 20080506 at 3.) In making the rejection, the Examiner referred to the claims of Goehl and asserted that "claim 1 ... shows a tubular membrane prepared as in claims 3, 5 and 8, which claims are pertinent to the extent of their disclosure of the mixture claimed herein, i.e. polymer and inulin, capable of being extruded." (Id.)

The disclosure of Goehl was summarized in the prior Response at pages 6-7.

To further prosecution, claim 14 has been amended to recite that the "thermoplastically processable material [is] obtained by extrusion at a temperature of

from 80 °C to 200 °C in the presence of water and/or a plasticizer containing hydroxyl groups."

Arguments presented in the prior Response on pages 7-8 are incorporated here as if presented in full. The Examiner's attention is drawn to these previously made arguments in conjunction with the present amendment of claim 14.

It is also noted that the Examiner has erred in making assertions regarding Goehl (and about applicants' arguments regarding Goehl) in the Examiner's response to Arguments section on page 8 of the Action. The Examiner asserted that "[w]ith regard to 'Goehl', applicant states that the patentee extrudes to obtain a sheet and the sheet does not contain inulin in the thermoplastically processable form." (Id.) The Examiner further asserted that this "translates into being capable of being processed thermoplastically." (Id.)

It is submitted, however, that Goehl discloses a membrane obtained from a polycarbonate solution *in an organic solvent* to which inulin can be added as a *swelling agent*. (See Examples 1-3.) Goehl is concerned with the ultrafiltration rate of the resultant membrane. (See, e.g., Page 8.) In Goehl, the solution is extruded to obtain a flat sheet, tubular, or hollow fiber membrane, and the membrane *does not* contain inulin in *thermoplastically processable form, according to the disclosure of Goehl, due to the absence of water and/or a polyol plasticizer during extrusion*.

Because Goehl fails to disclose each and every element of amended claim 14, the anticipation rejection has been rendered moot and should be withdrawn.

2. Claim 14 in view of Soon-Shiong

Claim 14 was rejected under 35 U.S.C. § 102(b) as being anticipated by WO 93/09176 ("Soon-Shiong"). (Id.) In making the rejection, the Examiner referred to claims 1-5 of Soon-Shiong and asserted that "[c]laim 1 describes a polysaccharide given as inulin in claim 5, which contains a moiety which will undergo polymerization. Therefore, the material is a combination of inulin and a polymer and is 'thermochemically processable'." (Id.)

The disclosure of Soon-Shiong is summarized on pages 8-9 of the prior Response.

To further prosecution, claim 14 has been amended to recite that the "thermoplastically processable material [is] obtained by extrusion at a temperature of from 80 °C to 200 °C in the presence of water and/or a plasticizer containing hydroxyl groups."

Arguments presented in the prior Response on pages 9-10 are incorporated here as if presented in full. The Examiner's attention is drawn to these previously made arguments in conjunction with the present amendment of claim 14.

In the Response to Arguments section of the Action, the Examiner asserted that "Soon-Shiong has been criticized for disclosing a biocompatible material and not a "chewable" article. If the two elements claimed are present, then they must be capable of being chewed on as well, and therefore, must be "chewable". Finding one more property, i.e. of being "chewable" does nothing to a combination already known and old in the art." (Id. at 9.)

Soon-Shiong discloses a modified biocompatible material of formula A-X, wherein A can be inulin and X is a **moiety** capable of free radical polymerization. (See claims 1-5). That, however, is **not** what is presently claimed. The material in Soon-Shiong is a compound having the formula A-X, which is **not** inulin. Moreover, it is also **not** "[a] thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers" as currently claimed.

The Examiner has pointed to no example in Soon-Shiong using inulin as a thermoplastically processable inulin or mixtures of inulin and/or oligofructans. Indeed, no such example can be found.

Furthermore, inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable **because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C**, as presently claimed. (See, e.g., Specification at page 4, line 24 to page 5, line 3; and claim 12 or original claim 6 as in WO 00/54578).

Nor has the Examiner pointed to any disclosure in Soon-Shiong of "chewable articles" as claimed.

For each of the foregoing reasons, Soon-Shiong does not disclose each and every element of the claimed invention. Thus, it is respectfully submitted that the rejection fails to present a *prima facie* case for anticipation and must be withdrawn.

### 3. Claim 14 in view of Guttag

Claim 14 was rejected under 35 U.S.C. § 102(b) as being anticipated by Guttag U.S. Patent No. 5,346,929. (Guttag"). (Id.) In making the rejection, the

Examiner reasserted from the prior rejection, "See claims 1 and 11 that recite inulin with polymers. 'Chewable article for animals' is use terminology.... Since inulin is the same, then it is inherently 'thermoplastically processable'." (Id.) In the present Action, the Examiner asserted in addition that "[c]laim 1 recites a synthetic polymer and a natural polymer, which claim 11 recites is an inulin, synthetic polymers described at col. 4, lines 10-16. The claim requires two elements, inulin and thermoplastic polymers." (Id. at 4.)

Guttag is summarized in the prior Response on page 10.

To further prosecution, claim 14 has been amended to recite that the "thermoplastically processable material [is] obtained by extrusion at a temperature of from 80 °C to 200 °C in the presence of water and/or a plasticizer containing hydroxyl groups."

Arguments presented in the prior Response on pages 10-12 are incorporated here as if presented in full. The Examiner's attention is drawn to these previously made arguments in conjunction with the present amendment of claim 14. In short, the molded articles obtainable from the plastic material of Guttag cannot contain inulin as presently recited in claim 14 due to the nature of the synthetic polymer used, which synthetic polymers were cited by the Examiner (Id. at 4, citing Guttag col. 4, lines 11-16). The presently claimed thermoplastically processable material which is obtained by extrusion at a temperature of from 80 °C to 200 °C in the presence of water or a plasticizer containing hydroxyl groups cannot be anticipated by Guttag which uses a synthetic polymer the extrusion of which excludes the presence of water and/or polyol plasticizers.

Guttag does not disclose each and every element of the claimed invention. It is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

4. Claim 14 in view of Van Haveren

Claim 14 was rejected under 35 U.S.C. § 102(e) as being anticipated by Van Haveren et al. U.S. Patent No. 6,313,203 ("Van Haveren"). (Id.) As in the prior Action, the Examiner asserted that "[t]he claims show a mixture of a thermoplastic polymer with inulin. See claim 4." (Id.) In the present Action, the Examiner also asserted, "See col. 2, lines 10-11 that describe inulin as being the polyfructose (claim 1), which is a known fact in basic chemistry." (Id.)

The disclosure of Van Haveren has been summarized on page 12 of the prior Response.

The present amendment to claim 14 is noted above.

Arguments presented on behalf of applicants from page 12 to 13 are incorporated here in full.

We acknowledge the Examiner's response on page 10 of the present Action in which the Examiner asserted that "it cannot be said that applicant has perfected his foreign priority date. Until such time, the [rejection made over Van Haveren is] deemed proper and valid and cannot be withdrawn."

We respectfully submit that the intent is to perfect priority.

***Obviousness Rejection***

Claims 1, 4, 7, 10-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Leo U.S. Patent No. 5,419,283 ("Leo") and Wang U.S. Patent No. 5,922,379 ("Wang") in view of Anantharaman et al. U.S. Patent No. 5,952,033 ("Anantharaman") and further in view of Van Haveren et al. U.S. Patent No. 6,313,203 ("Van Haveren") and Bengs et al. U.S. Patent No. 6,406,530 ("Bengs"). (Id. at 4.)

The disclosures of Leo, Wang, Anantharaman, Van Haveren, and Bengs are summarized in the prior Action on pages 14-15.

In making the rejection, the Examiner reasserted arguments in the present Action on page 4-7 which were presented in the prior Action, also from page 4-7. These assertions of the Examiner were briefly summarized on pages 15-16 of the prior Action.

The arguments presented on behalf of applicants from pages 16-22 in the prior Response are incorporated here in full.

The Examiner also provided assertions in the Response to Arguments section regarding the obviousness rejection from page 10-12. The Examiner asserted, *inter alia*:

The references of Van Haveren and Bengs provide strong motivation to modify the primary references that already disclose thermoplastic polymers. Further Anantharaman shows that inulin provides an additional benefit. While applicant insists that his invention is unobvious because the extrusion was conducted with water and/or a plasticizer, the references clearly establish that there was sufficient motivation to combine them, as stated above. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious....

Again, applicant is reminded that the terms "processable" and "chewable" are interpreted as being "capable of being processed or chewed, respectively. And again, the claims herein are to a product and not to a process. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.... (Id. at 11.)

As is indicated in the arguments presented in the prior Response, Bengs and Van Haveren are not proper references. As noted above in response to the anticipation rejection over Van Haveren (section 4 above), we acknowledge the Examiner's response on page 10 of the present Action in which the Examiner asserted that "it cannot be said that applicant has perfected his foreign priority date. Until such time, the rejections made over these references (Van Haveren and Bengs) are deemed proper and valid and cannot be withdrawn."

We respectfully submit that the intent is to perfect priority.

Beyond looking at the references to determine if any of them suggests doing what the inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) ("Both the suggestion and the expectation of success must be founded in the prior art, not in applicants' disclosure.") "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the U.S. Patent and Trademark Office Examination Guidelines at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in



the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge". However, no such motivation or expectation of success can be found in the cited documents.

Initially, we submit that the Examiner has erred in characterizing the arguments submitted in the prior Response. As cited above, the Examiner asserted that "... applicant insists that his invention is unobvious because the extrusion was conducted with water and/or a plasticizer...". (Id. at 11.) Although the extrusion disclosed in the present application for use in preparing the claimed chewable articles is conducted in this manner, the Examiner has mistaken this as the "reason" that the rejection should be removed. The Examiner has missed the mark. It is respectfully submitted that the cited references do not disclose or suggest the claimed invention. Moreover, one skilled in the art would not have had an expectation of success in achieving the claimed chewable article made from thermoplastically processable inulin or mixtures of inulin and/or oligofructans with thermoplastic polymers. Because of the Examiner's error, for this reason alone the rejection should be withdrawn.

Although Leo discloses the use of starch and Wang discloses the use of a starch-protein/thermoplastic composition, the claimed chewable article comprises an inulin which is a polysaccharide. The polysaccharide inulin differs completely from a starch in both structure and molecular mass, as noted in the prior Response. The degree of polymerization of inulin is only between 2 and 60, whereas the degree of polymerization for starch is orders of magnitude higher. The Examiner has erroneously ignored that ***one would not be motivated to use inulin because its molecular mass***

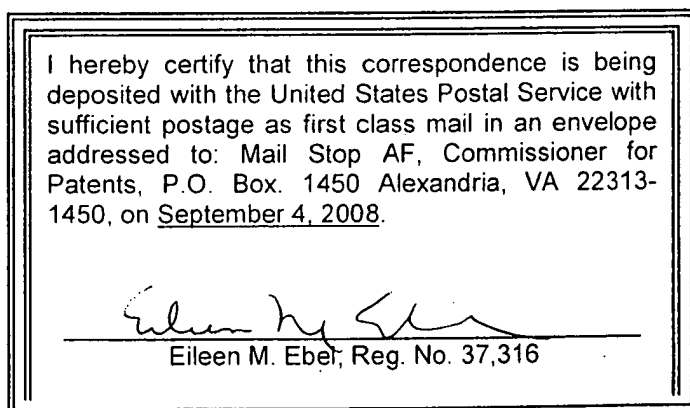
***is so low that one skilled in the art would not expect success in converting it into a thermoplastically processable material.***

Anantharaman does not in any way suggest use of inulin as a thermoplastically processable material. In no way does Anantharaman alter the lack of expectation of success on the part of one skilled in the art in achieving the claimed invention, as noted above.

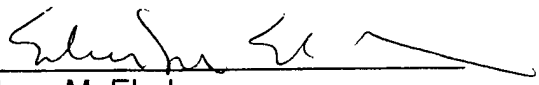
Neither Leo, Wang, or Anantharaman, alone or in any combination, render obvious the claimed invention.

It is respectfully submitted that the rejection has been overcome. Reconsideration and withdrawal of the rejection are requested.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.



Respectfully submitted,

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